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10/544,897	02/02/2006	Ralf Dunkel	CS-8582/LeA 36,354	6478
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Patent Department 2 T. W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709			HAVLIN, ROBERT H	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/544,897 DUNKEL ET AL. Office Action Summary Examiner Art Unit ROBERT HAVLIN 1626 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 25 February 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 19-22.27.28.32 and 33 is/are pending in the application. 4a) Of the above claim(s) 27 and 32 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 19-22,28 and 33 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

Status of the claims: Claims 19-22, 27-28, 32, and 33 are currently pending. Claims 27, and 32 are withdrawn.

**Priority:** This application is a 371of PCT/EP04/01053, filed on February 5, 2004 and claims benefit under 35 U.S.C. 119(a)-(d) to foreign applications Germany 10306244.0, filed February 14, 2003 and Germany 10321270.1, filed May 13, 2003.

Restriction: Applicant elected group I (claims 19-26, 28, 31-33, drawn to compounds of formulae I, IV, VI, and VIII) in the telephone inquiry on March 29, 2007. The examiner further required an election of a single species on the telephone with Mr. Henderson on 4/2/2008. The following form paragraph reflects this requirement.

# Species election form paragraph

Claim 19 is generic to the disclosed patentably distinct species listed in table 1.

The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant has elected a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

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not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant has not traversed the election of species requirement. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant elected the species # 39 (of the amended specification) of the formula

(where Z=1-methylbutyl) over the phone on 4/2/2008 with Mr.

Henderson.

In accordance with the election of species, no generic claim was allowable, therefore the scope of the claims were restricted to the elected species only. Thus

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subject matter not reading on the elected species is held withdrawn until a generic claim is found allowable. As a result, because claims 27, and 32 do not read on the elected species, they are withdrawn in their entirety.

## Declarations:

The declaration of 2/25/08 filed under 37 CFR 1.132 is insufficient to overcome the rejection of claims 19-22, 28, and 33 based upon 35 USC 103(a) as set forth in the last Office action because: although the document showed an efficacy comparison between the prior art compound of Hahn et al. (where Z=isopropyl) vs. compound 102 (Z=3-methylbutyl), the document does not show unexpected results. First, example 102 differs from the elected species and is presently outside the scope under consideration. Second, Hahn et al. teaches numerous alkyl substitutions on the phenyl group each have substantial activity, thereby indicating that the expected result would be that alkyl substitutions on the phenyl group make for good fungicides. Third, the differences in efficacy do not rise to the level of unexpected results in view of the teachings of Hahn et al. Therefore, applicant has failed to show any unexpected result to overcome any obviousness rejection.

#### RCF:

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been

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withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/08 has been entered.

#### Rejections in Prior Office Action

- Claims 19-22, and 28 were rejected under 35 U.S.C. 102(b) as being aniticipated by Hahn et al. (Han'guk Nonghwa Hakhoechi (2001), 44(3), p. 191-196). This rejection is withdrawn because the claims were amended to avoid anticipation.
- Claims 19-22, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al. This rejection is maintained and elaborated below.

## Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 19-22 and 28 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-14, and 17 of copending Application No. 10/576153. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because the copending application claims a similar generic core and discloses species in support of that core which are obvious variants of the elected species such as compound 20:



which differs from the instant claims by only by a trifluoromethyl

group which is claimed in both applications.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

 Claims 19-22 and 28 are rejected under 35 USC 112 1<sup>st</sup> paragraph as failing to comply with the written description requirement.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that (the inventor) invented what is claimed."). Thus, an applicant

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complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly* & Co. the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Fiers, 984 F.2d at 1171, 25 USPQ2d 1601; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad genus. In Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically state that for each claim drawn to a genus the written description requirement may be satisfied through sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to

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drawings or structural chemical formulas; c) disclosure of relevant, identifying characteristics (ie. structure) by functional characteristics coupled with a known or disclosed correlation between function and structure. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention (Federal Register, Vol. 66, No. 4, p. 1105, 3<sup>rd</sup> column, 3<sup>rd</sup> paragraph). Below is such comparison.

It is noted that in the following the comparison is focused on products and not method of use. It is to be understood, however, that a *prima facie* conclusion of lack of written description for product implies the same conclusion for the process of use. In other words, the process of use cannot be practiced in absence of the product.

# I. Scope of Claims (based on elected subject matter)

Compounds of Formula I:

$$G^{2} \xrightarrow{S} \bigcap_{G^{1}} \bigcap_{R^{5}} \bigcap_{Z} \bigcap_{R^{4}} \bigcap_{R^{5}} \bigcap_{Z} \bigcap_{R^{5}} \bigcap$$

The following variables are claimed <u>broader</u> than what is supported by the disclosure (see below section II):

Z, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>: for claims 19-22 and 28 R<sup>5</sup>: for claims 19, 20, 22 and 28 G<sup>1</sup>: for claims 19-22 and 28 G<sup>2</sup>. G<sup>3</sup>. n: for claims 19-22 and 28 G<sup>2</sup>. G<sup>3</sup>. n: for claims 19, 21, 22 and 28

## II. Scope of Disclosure

#### Reduction to Practice:

The compounds reduced to practice support the following definitions:

 $R^1$ : H

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R<sup>2</sup>: H, F R<sup>3</sup>: H, F, Cl

R<sup>4</sup>: H, alkyl-Z(cyclic) R<sup>5</sup>: H, COCH3 n: 0, 2

G1: CF3, cyclopropyl G2, G3: H, Me Z: Z2, Z3, Z4

Z3: unsubstituted C5-C10-alkyl

Z4: 1-methyl-3-butenyl; 1,3-dimethyl-1-butenyl; 3,3-dimethyl-1-

butynyl

# Reduction to Structural or Chemical Formulas:

The only disclosure, in addition to the species reduced to practice, is in form of a *list* of possible substituents for each variable. This type of disclosure is not viewed to be a representation of any of the species it entails. A"laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. MPEP 2163.I.A. and *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Therefore, there is no disclosure of species (eg. by reduction to structural/chemical formulas) in addition to those reduced to practice.

## Correlation between Structure and Function:

Furthermore, the instant specification does not disclose any correlation between function and structure. Thus, it is not understood what <u>specific structural</u> elements are essential for the activity of the instantly claimed compounds.

# III. Analysis of Fulfillment of Written Description Requirement:

In the absence of a correlation between structure (as it pertains to variables R<sup>1</sup>-R<sup>3</sup>) and function, it is not possible to predict what modifications will allow for the preservation of the desired activity.

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In conclusion: (i) substantial structural variation exists in the genus/subgenus embraced by claims 19-22 and 28; (ii) disclosure of species supporting genus is limited to compounds reduced to practice, which scope is not commensurate with the scope of genus/subgenus claimed; (iii) common structural attributes of the claimed genus/subgenus, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art. Thus, the specification fails to provide adequate written description for the genus of compounds claimed and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

# Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be neadtived by the manner in which the invention was made.
- 4. Claims 19-22, 28, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al. (Han'guk Nonghwa Hakhoechi (2001), 44(3), p. 191-196). The elected species in the instant application has the structure:

While the prior art Hahn et al. teaches the compound (#53 in table 1):

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#### Difference between the prior art and the claims

Thus the difference between the prior art and elected species is two additional methylene groups on the isopropyl group of Hahn's compound.

## Finding of prima facie obviousness

The prior art reference teaches the compound #53 as a fungicidal compound and the abstract points to a positional isomer at the meta position (instead of the ortho position as in #53) as having excellent antifungal activity. In addition, the activities of the compounds listed in Table 1 suggest that alternative alkyl substitutions on the phenyl ring will produce compounds with similar activity. Thus one of ordinary skill in the art would be motivated to make homologs and positional isomers of the compounds taught by Hahn et al.

This is further supported by caselaw and the MPEP in section 2144.09(II):

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977); see also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the teachings of Hahn et al. by adding two methylene groups on the alkyl group of compound # 53 to arrive at the elected species of the instant application.

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Although applicant has submitted a declaration indicating the capabilities of example 102 is superior to compound 53 of Hahn et al., this is insufficient to overcome this obviousness rejection. First, example 102 differs from the elected species and is presently outside the scope under consideration. Second, Hahn et al. teaches numerous alkyl substitutions on the phenyl group each have substantial activity, thereby indicating that the expected result would be that alkyl substitutions on the phenyl group make for good fungicides. Therefore, applicant has failed to show any unexpected result to overcome any obviousness rejection.

#### Conclusion

The claims are not in condition for allowance.

# Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Robert Havlin/ Examiner, Art Unit 1626 /Rebecca L Anderson/ Primary Examiner, Art Unit 1626